## REMARKS

In response to the Office Action dated December 2, 2005, reconsideration of the application is respectfully requested in view of the pending claims and the following remarks.

### I. The Pending Claims

Prior to this amendment, claims 1 and 53-69 were pending in the application. In response to the Office Action, claims 1, 55, 57-59, 65-69 are amended. Accordingly, upon entry of this amendment, claims 1, and 53-69 remain pending in the application and are believed to be in proper condition for allowance.

### II. Amendment to the Title

The Title of the Invention is amended for clearly indicative of the invention to which the claims are directed. The Title of the Invention is read as follows:

*"COLLECTION DEVICE FOR ASSAY OF ORAL FLUIDS."*

### III. Rejection under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 55-59, 65-67 and 69 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 55, 57-59, 65-69 are amended to address the issues raised by the Examiner in the Office Action.

In view of the amendments above and the comments below, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 55 and 65 were rejected as being confusing because the position of the conjugate strip relative to the blocking strip is unclear. Claims 55 and 65 were amended to clarify the position of the conjugate strip. Support can be found in the specification (see, e.g., Fig. 1, p. 9, lines 26-29 of the specification).

Claim 57 was rejected as being indefinite because of an improper Markush grouping. Claims 57-59 were amended to correct the language of the Markush groups recited in these claims.

Claim 66 was rejected as being vague with respect to how the housing is connected to the capillary matrix. Claims 66 was amended to clarify the connection between the housing and the capillary matrix.

Claim 67 was rejected as being incomplete and claim 67 was amended for clarity.

Claims 68-69 were rejected as being vague and claims 67-69 were amended to replace "an apparatus" with "the apparatus" for clarity.

**IV. Rejection under 35 U.S.C. § 103 and 102(e)**

*A. Rejection of claims 1, 55-58, 60-61 and 63-69 under 35 U.S.C. §§ 102(e) and 103(a)*

Claims 1, 55-58, 60-61 and 63-69 were rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Moorman (U.S. Patent No. 5,820,826). The Examiner stated that Moorman discloses a device comprising a capillary matrix (26) having an exposed surface for receiving a test fluid (column 10, lines 22-23), substrate pad (27) having assay reagents (column 10, lines 23-27), blockings strips including tape and a one-way flow regulating means located between the capillary matrix and the chromatography strip (column 10, lines 28-32). According to the Examiner, Moorman teaches that assay reagents may be dried into the pores of the blocking strip, (column 11, lines 12-21) and with respect to claims 63, 65 and 67, that the apparatus is placed on an inert support or housing (column 5, lines 45-47 and column 11, lines 39-40), which meets the limitation that the chromatography strip extends into the cavity of the housing or the at least partially disposed in the housing. The Examiner further asserted that Moorman teaches that additional features such as antibodies, signal inhibitors, buffers and so forth may be incorporated into the apparatus (column 11, lines 48-51), that the device is capable of detecting analytes such as HIV antibodies, Rubella, etc., and kits comprising the device, buffers and reagents for detection of analytes, (column 26, lines 1-9).

The Examiner explained that even though Moorman does not specifically disclose oral fluids, this limitation is seen to be an intended use of the claimed device and is not afforded patentable weight. Further, the Examiner stated that Moorman does not specifically call the collection matrix "paddle-shaped", however, since the specification does not specifically state the shape or composition of the "paddle-shaped" matrix, only that it has a certain surface area, the collection matrix taught by Moorman is seen to anticipate this limitation.

Applicants respectfully traverse this rejection.

As set out in claim 1, the claimed invention recites a combination of elements including a capillary matrix having an exposed surface for receiving oral fluid, a lateral flow chromatography strip where the lateral flow chromatography strip is in communication with

the capillary matrix, and a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent.

Moorman discloses a casing for a diagnostic test strip containing two openings. One of the openings is defined by four sides, two of which, positioned opposite each other, terminate in a ridge and the ridge terminates short of the point where the diagnostic test strip is placed (Moorman, Abstract, column 15, lines 29-33 and claim 1). The small gap assists in metering liquid to the diagnostic test strip (Moorman, Abstract and column 15, lines 29-33). The entire apparatus of Moorman is placed on an inert support (30) to give added strength to the apparatus (Moorman, column 11, lines 39-41). The method of attachment of the strip components to the inert support may involve the use of double stick tape, hardened hot melt adhesives, a combination of the two, and/or other materials with suitable adhesive properties, all of which are known to the art (column 11, lines 43-48). Moorman also discloses that test apparatus are advantageously kept in a casing in order to not only provide protection to the test strip and safety to the user, but also facilitate the use of the device in carrying out test analysis (Moorman, column 14, lines 41-45).

More specifically, Moorman discloses that a substrate pad (27) is separated from the absorptive material (26) by a piece of double stick tape (28). A second piece of double stick tape (28') separates the substrate pad (27) from flow regulating means (29), which is in turn in one-way fluid contact with the test strip 11 (Moorman, column 10, lines 21-32). According to Moorman, double stick tape (28) is provided to guarantee that the liquid goes only into the front end of the substrate pad, so that this blocks the liquid from going forward, forcing it to move down and into the substrate pad (Moorman, column 10, lines 33-54). Further, Moorman discloses that additional types of blocking materials may be employed for this purpose, such as hardened hot melt adhesives (Moorman, column 10, lines 55-58). The second block or piece of double stick tape (28') prevents the liquid from flowing backward (Moorman, column 10, lines 58-61).

Disclosing entirely different blocking materials, Moorman does not teach or suggest a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent, as the claimed invention. Moorman's double stick tape is not intended to function as blocking strip or does not contain at least one blocking agent. Rather, the placement of tape 28' directs the flow of solubilized substrate into the structure "29", referred to herein as a flow regulator or flow directing means (Moorman, column 11, lines 1-3), which only permits flow of liquid

downward, because of the configuration of its pores (Moorman, column 11, lines 4-6). This flow director 29 is in fluid contact with the matrix 11, so the solubilized/mobilized substrate moves unilaterally into the matrix (Moorman, column 11, lines 9-11).

Furthermore, Moorman appears to teach away from a capillary matrix having exposed a surface for receiving oral fluid as Moorman discloses that a casing or holder for a test strip which protects the test strip (Moorman, column 6, lines 27-28) and the sealing of casing parts creates discrete overlfow compartments resulting in retention of the excess fluid (such as sample and reagents) in the compartment immediately adjacent to the application point until the test strip is ready to absorb it (Moorman, column 15, lines 47-52).

For the reasons discussed Moorman neither anticipates, nor would it have rendered obvious Applicants' claimed invention. Applicants respectfully request the withdrawal of this rejection and the allowance of claims.

*B. Rejection of claims 1, 53, 55-58, 60-61 and 63-69 under 35 U.S.C. 103(a)*

Claims 1, 53, 55-58, 60-61 and 63-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer (U.S. Patent No. 4,635,488) in view of Sangha (U.S. Patent No. 5,334,502) and de Zoeten et al (U.S. Patent No. 5,611,995). The Examiner stated that Kremer discloses a sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in the open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the last mentioned end of the tube for contact with a fluid to be collected. According to the Examiner, the nib comprises a solid, nonfibrous, porous, water-wetable body having porosity sufficient for absorption of the fluid to be collected and the nib is a unitary molded plastic body made of polyethylene or polypropylene and is treated with a wetting agent to impart water-wettability (column 2, line 48-68 and column 3, lines 1-9).

The Examiner also stated that the device of Kremer is provided with a cap for closing the open end of the tube and with an elongated, absorbent and rigid analysis element having an agent that undergoes an observable change upon contact with a substance to be detected in a body fluid sample. According to the Examiner, the analysis element has a proximal end mounted in the cap, such that when the cap is in position closing the open end of the tube, the analysis element extends through the tube and its distal end is in fluid transferring contact with the inner extremity of the nib to receive and absorb fluid collected by the nib. The Examiner asserted that the distal end of the analysis element may be anchored in the nib, or

may comprise a body of porous material arranged for contact with the inner extremity of the nib so that transfer of the sample from the nib to the analysis element by absorption occurs only after collection of the sample by the nib has been completed (column 3, lines 26-50).

The Examiner explained that in one embodiment, the device having an analysis element, either in particulate form or strip form, also comprises an absorbent but hydrophobic body situated between the nib and the analysis element to prevent premature transfer of samples to the analysis element (column 3, lines 59-65, column 10, lines 53-68, and Fig. 16). According to the Examiner, Kremer discloses that the nib absorbs and retains a fluid sample by wicking or capillary action and should be contacted with, for example, the tongue until the nib is completely saturated with the body fluid; since a given porous nib has an essentially fixed fluid capacity, saturation assures collection of a sample of predetermined volume (column 7, lines 7-23).

The Examiner concluded that Kremer discloses that porous nibs may be purchased from Porex Technologies (column 5, lines 25-28) and the device also comprises a transparent sidewall for visual observation of the color change (column 8, lines 61-66). The Examiner acknowledged that Kremer differs from the instant claims in failing to teach a blocking strip comprising blocking agents and detergents or buffers.

The Examiner asserted that Sangha discloses a method and device for saliva specimen collection comprising a capillary tube surrounding an absorbent pad and on top of the absorbent pad is a one-way barrier having indicator component. According to the Examiner, as saliva migrates or is wicked along the absorbent pad, it approaches and passes through the one-way barrier to interact with the indicator component. The Examiner stated that once the saliva has passed upwardly through the barrier, the saliva is unable to migrate back through the barrier, thus contact between the subject and the saliva that has interacted with the indicator is avoided (column 9, lines 37-50). The Examiner asserted that Sangha also discloses a test card for detecting analytes in a saliva sample comprising tretramethylbenzidine (TMB) dissolved in dimethyl formamide (DMF) or dimethyl sulfoxide (DMSO) and EDTA impregnated thereon and dried (column 15, lines 13-27).

According to the Examiner, De Zoeten discloses an apparatus having a housing and holding device thereon for holding a test strip comprising a sample collector which can readily absorb test liquid, but also easily release the liquid under capillary transfer. The Examiner stated that the sample collector is made of material such as polypropylene, and to this material can be added, reagents such as buffering compounds to adjust the pH of the test

liquid or compounds able to eliminate interfering substances present in the test liquid (column 4, lines 40-59) and conventional blocking agents such as polyvinylalcohol, or human and bovine serum albumin (column 7, lines 5-14).

Therefore, the Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to place reagents such as buffers and detergent taught by Sangha and de Zoeten in the device of Kremer because Sangha and de Zoeten teach that such reagents are well known in the art as providing the advantage of improving assay results by maintaining appropriate pH of the sample and dissolving interference material prior to contacting the sample with the test reagents.

The Examiner also concluded that a skilled artisan would have had a reasonable expectation of success in placing these reagents on the strip of Kremer because Sangha teaches a blocking strip made of the same material as that of Kremer which can incorporate reagents such as dyes, and de Zoeten teaches adding buffering compounds to a sample collector (also made of the same material) to adjust pH of the test liquid and therefore, absent unexpected results, these limitations are seen to be obvious in view of the teachings of Kremer as modified by Sangha and de Zoeten.

This rejection is respectfully traversed.

None of these references, alone or in combination, suggest an apparatus for collection and lateral flow chromatography of oral fluid, in particular, a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent. Furthermore, there is no motivation to combine these references in the manner suggested by the Examiner, and even if there was motivation, such a combination still fails to result in the present invention as set forth below.

Kremer is directed to a body fluid sampling device comprising a hollow tube having at least one open end, and a collecting nib secured in that open end of the tube and having an inner extremity facing the interior of the tube and an outer tip projecting beyond the end of the tube for contact with a fluid to be collected (Kremer, column 2, lines 50-55). As the Examiner acknowledged in the Office Action, Kremer does not disclose, teach or suggest a blocking strip comprising blocking agents and detergents or buffers (Office Action, page 6). Either Sangha or de Zoeten alone or in combination do not cure the deficiencies of Kremer as there are no teaching in either reference on blocking strip having at least one blocking agent as set forth below.

Sangha discloses a method for rapidly determining during a saliva specimen collection procedure the presence of an amount of saliva, and for verifying that the sample obtained is in fact saliva. Color indication by dye markers and/or enzymatic activation of color indicators provides an indication that at least a predetermined amount of saliva has been applied to an absorbent and the enzymatic reaction indicates that saliva is contained in the sample collected. In one embodiment, Sangha utilizes the method that peroxidase enzyme in saliva, in the presence of a peroxide, oxidizes the "leuco" or colorless form of a dye or other indicator to produce a colored form of the dye or indicator (Sangha, column 4, lines 14-19). The reaction of the saliva peroxidase with the indicator is used to determine that the sample is, in fact, saliva and also that sufficient sample has been placed on the absorbent (Sangha, column 4, lines 20-23). In another embodiment, Sangha utilizes the amylase enzyme of saliva to effect a color change, from colorless to colored, in a substrate compound. Upon being contacted by the amylase of saliva, the substrate reacts with the amylase to release the chromogen from the polysaccharide or oligosaccharide substrate to thereby provide a free chromogen which is colored and visible to an observer. Once sufficient saliva has been absorbed so as to allow sufficient saturation of the absorbent to result in saliva contacting and reacting with the indicator, the on-site examiner can easily observe the color change of the indicator or the diffusing or migration of the indicator in the saliva and be assured that sufficient sample has been placed on the absorbent (Sangha, column 4, lines 51-58).

The cited Sangha reference is completely silent as to blocking pad with blocking agents as specifically recited in claimed invention. In addition, Sangha does not disclose, teach or suggest the limitations as recited in the claimed invention of the present application. It is also respectfully noted that there is no specific teachings in Kremer nor Sangha to combine these references in the manner suggested by the Examiner. Sangha does not disclose or suggest the apparatus for collection and lateral flow chromatography of an oral fluid, but rather, discloses a method for rapidly determining the presence of a saliva and the amount of saliva collection. De Zoeten discloses an apparatus detects a specifically reacting substance in a test liquid having a housing and a holding device thereon for holding a test strip (de Zoeten, Abstract, column 2, lines 13-34). The test strip has a material that transports a test liquid essentially by capillary forces and has an analytical system which indicates the presence or absence of the substance to be detected (de Zoeten, column 2, lines 19-24). De Zoeten does not teach or suggest a blocking pad containing the blocking agents, but rather discloses that the binding reagents such as antibodies or avidin can be immobilized onto the

test strip by covalent binding or absorption and after coupling, the remaining binding sites on the test strip should be blocked with, for example, treatment with hydrophilic synthetic polymers, such as polyvinylalcohol, or hydrophylic biopolymers, such as human and bovine serum albumin, ovalbumin and the like (de Zoeten, column 7, lines 7-14). If the test strip consists of other materials such as paper, covalent coupling can be achieved with CNBr or carbonyldiimidazole (de Zoeten, column 7, lines 7-14). Therefore, de Zoeten reference is also completely silent as to blocking pad with blocking agents as specifically recited in claimed invention. In addition, de Zoeten does not disclose, teach or suggest the limitations as recited in the claimed invention of the present application and there is no specific teachings in Kremer nor de Zoeten to combine these references in the manner suggested by the Examiner.

Accordingly, Sangha or De Zoeten alone or in combination fails to remedy the deficiencies of Kremer in that both references also fail to disclose a blocking strip containing at least one blocking agent. Applicants' claimed invention would not have been obvious from the teachings of the combination of Kremer in view of Sangha and de Zoeten et al. Applicants respectfully request the withdrawal of this rejection and the allowance of claims.

C. *Rejection of claim 62 under 35 U.S.C. 103(a)*

Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kremer or Moorman in view of Sangha and de Zoeten and further in view of Porex Technologies Catalog, 1995. The Examiner asserted that although Kremer, Sangha and de Zoeten differ from the instant claim in failing to teach a capillary matrix having an average pore size from about 40 to 250μm, Porex discloses porous plastics available in molded shapes, sheets, rods and tubes having an average pore size from 7 to greater than 250 micrometers. The Examiner further asserted that Porex engineers can also develop custom designs for specific use which will take into consideration strength, sample flow, durability and shape (pages 1, 3, 8 and 24-25).

The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose a porous nib with the desired pore size such as taught by Porex for use in the device of Kremer or Moorman as modified by Sangha and de Zoeten because this parameters are dependent on the nature of the assay, i.e. samples to be tested and reagents involved. The Examiner further asserted that a skilled artisan would have had a reasonable expectation of success in choosing from any of the disclosed nibs or to have nibs specification made to fit their needs. According to the Examiner, the selection of a

specific material is generally dependent on the assay and the characteristics of the sample, therefore, absent unexpected or improved results, selection of nibs with specific pore sizes so as to optimize the performance of a device is seen to be obvious in view of the teachings of Kremer or Moorman and Porex Technologies.

Applicants respectfully traverse this rejection and request reconsideration.

As set forth above remarks in sections A and B, there is no teaching of an apparatus for collection and lateral flow chromatography of an oral fluid sample having a blocking strip containing at least one blocking agent in Moorman, Kremer, Sangha, or de Zoeten alone or in combination. Not teaching a blocking strip as recited in claim 65, Porex Technologies Catalog does not cure the deficiencies of those references. For the reasons discussed above, claim 65 would not have been obvious to one of ordinary skill from the references cited. Withdrawal of this rejection is respectfully requested.

*D. Rejection of claim 54 under 35 U.S.C. 103(a)*

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman as applied to claims 1, 55-58, 60-61 and 63-69 above, and further in view of Ching et al (U.S. Patent No. 5,120,643). The Examiner asserted that although Moorman differs from the instant claims because it fails to disclose that the blocking agents are bovine serum albumin, deoxycholate or n-lauroyl sarcosine, Ching, however, discloses that devices using labeled specific binding materials including colloidal particle and enzyme labeled materials which are dried onto a chromatographic medium in the presence of a meta-soluble protein are capable of being rapidly resolubilized in the presence of an appropriate solvent such as the sample (column 7, lines 3-10). The Examiner further asserted that Ching teaches impregnating solid substrate materials with meta-soluble proteins such as bovine serum albumin and detergents, e.g. sodium deoxycholate, etc. (column 22, lines 25-47).

The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the meta-soluble proteins taught by Ching to the blocking means or substrate pad of Moorman because Moorman teaches that additional features may be incorporated into the apparatus including antibodies, signal inhibitors, buffers and so forth (column 11, lines 49-51) and Ching teaches that improved assay results is achieved using the meta-soluble agents. The Examiner further asserted that a skilled artisan would have had a reasonable expectation of success in adding the meta-soluble agents of Ching to the device of Moorman because the addition of agents such as buffers and the like

are well known in the art as indicated by Moorman and the choice of appropriate agents is chosen on the basis of the aim of the assay and the type of the analytes.

Applicants respectfully disagree.

As discussed above, Moorman fails to disclose a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent. Moorman's blocking means, "double stick tape", was not intended to function as blocking strip nor contain at least one blocking agent. Instead, double stick tape directs the flow of solubilized substrate into the flow regulator or flow directing means by the placement of two double stick tapes, which only permit flow of liquid downward to the matrix.

Accordingly, Ching cannot remedy the deficiencies of Moorman because the combination of Moorman and Ching still fails to result in Applicants' claimed invention.

Ching is directed to specific binding assay methods, kits and devices utilizing chromatographically mobile specific binding reagents labelled with colloidal particles and specific binding reagents labelled with colloidal particles such as gold and selenium may be subjected to rapid chromatographic solvent transport on chromatographic media by means of selected solvents and chromatographic transport facilitating agents. Further, Ching disclosed that impregnation of solid substrate materials with labile protein materials including colloidal particle and enzyme labelled reagents in the presence of meta-soluble proteins provides for the rapid resolubilization of such materials which have been dried onto such substrate materials.

The cited Ching reference is completely silent as to blocking pad with blocking agents as specifically recited in claimed invention. In addition, Ching does not disclose, teach or suggest how to modify the teachings of Moorman to arrive at Applicants' claimed invention. There are no specific teachings in Moorman nor Ching to combine these references in the manner suggested by the Examiner and the combination of Moorman and Ching still would not have rendered obvious Applicants' claimed invention to one of ordinary skill.

Thus, the withdrawal of this rejection, and the allowance of these claims are respectfully requested.

*E. Rejection of Claim 59 under 35 U.S.C. 103(a)*

Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorman as applied to claims 1, 55-58, 60-61 and 63-69 above, and further in view of Ziegelmaier (U.S.

Patent No. 6,632,628). The Examiner asserted that although Moorman differs from the instant claims in failing to teach the detection of hepatitis, however, Moorman does teach that the analyte and the analyte specific receptors are chosen on the basis of the aim of the assay and discloses typical tests including assays for etiological agents for infectious diseases (column 23, lines 29-38).

The Examiner further asserted that Ziegelmaier discloses assays for etiological agents for infectious diseases such as HIV, rubella, hepatitis A and B, etc. (column 4, lines 1-6), therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Moorman to detect analytes such as hepatitis as taught by Ziegelmaier because Moorman teaches that its device may be used to detect a variety of different analytes including etiological agents for infectious diseases and Ziegelmaier teaches that etiological agents such as hepatitis are well known in the art and can be detected using immunoassays.

The Examiner concluded that because Moorman teaches that the analyte and the analyte specific receptors are chosen on the basis of the aim of the assay, one skilled in the art would have had a reasonable expectation of success in using the device of Moorman to detect hepatitis antigens or antibodies as taught by Ziegelmaier.

Applicants respectfully traverse this rejection.

As discussed above, Moorman fails to disclose a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent, as now claimed. Claim 59 is a dependent claim from claim 1. Therefore, Ziegelmaier can not cure the deficiencies of Moorman by combination of both references.

Ziegelmaier disclosed an immunochemical method for the determination of antibodies which are specific for an antigen and are of one of the immunoglobulin classes A, M, D or E in a fluid, with this fluid being contacted with a solid phase to which the antibodies against this immunoglobulin class, or a fragment of an antibody of this type, are bound, which results in the immunoglobulin of this class being bound to this solid phase, and this solid phase being contacted with the antigen, which carries a labeling means where appropriate, and with a labeled antibody or a labeled fragment of an antibody against the antigen if the antigen is unlabeled and determination, from the amount of labeling means which is bound to the solid phase, of the amount of these antibodies which are specific for an antigen and are one of the immunoglobulin classes, which comprises the solid phase being simultaneously in contact

with the fluid containing the antibody which is to be determined and with the antigen, which is labeled where appropriate, there being addition of a substance which prevents immunoglobulin G binding to the solid phase and, where appropriate, antigen binding to immunoglobulin G.

According to Ziegelmaier, the object was to shorten and simplify the direct assay and to eliminate the competition between non-antigen-specific and antigen-specific immunoglobulins in order to permit reliable quantitative determination of the antigen-specific antibody fraction (column 2, lines 47-51) and this was achieved by eliminating the antigen-specific IgG antibodies (column 2, lines 59-62) and the activity of rheumatoid factors belonging to various immunoglobulin classes (column 3, lines 1-3).

Ziegelmaier is completely silent to as to blocking pad with blocking agents as specifically recited in claimed invention. Accordingly, even if Ziegelmaier is combined with Moorman in the manner suggested by the Examiner, such combination will still fail to disclose, teach, or otherwise suggest a blocking strip coupled between the capillary matrix and the lateral flow chromatographic strip, wherein the blocking strip contains at least one blocking agent.

Claim 59 would not have been obvious to one of ordinary skill from the teachings of Moorman or Ziegelmaier, alone or in combination. Applicants respectfully request the rejection be withdrawn.

## V. Nonstatutory Double Patenting Rejection

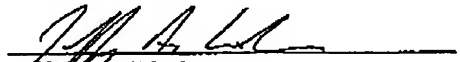
The Examiner provisionally rejected claims 1, 53, 55-61 and 63-69 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-80 and 51-53 of copending Application No. 09/973,956. The Examiner asserted that although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming a device for collecting and assay of analytes in oral fluids comprising a housing, a collection pad coupled to a chromatographic strip having appropriate reagents. The Examiner further asserted that the device also comprises a blocking strips with blocking agents or buffers. The Examiner indicated that the present double patenting rejection is a provisional rejection because the conflicting claims have not yet been patented.

As such, Applicants respectfully request that further response or the filing of a Terminal Disclaimer to overcome the provisional rejection based on the nonstatutory double patenting ground be deferred until no other issues with regard to patentability remain.

Applicants appreciate the Examiner's explanation regarding preservation of rights and the requirement of common ownership of the conflicting applications.

For the foregoing reasons, Applicant believes that the application now in condition for allowance and a notice to that effect is respectfully requested. However, if the Examiner deems that any issue remains after considering this response, he is invited to call the undersigned to expedite the prosecution and work out any such issue by telephone.

Respectfully submitted,



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